UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MARIA ROBINSON,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION H- 20-03760
	§	
ETHICON, INC. and JOHNSON & JOHNSON,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is a motion to exclude the expert testimony of Christina Pramudji, M.D., by plaintiff Maria Robinson. Dkt. 132. After considering the motion, response, and applicable law, the court is of the opinion that the motion should be DENIED.

I. BACKGROUND

Robinson had a device called TVT-O, comprised of mesh, surgically implanted on October 27, 2011. Dkt. 132, Ex. 1. The purpose of the surgery was to treat stress urinary incontinence ("SUI"). Dkt. 132. Robinson claims that the device caused significant medical problems, and she has had multiple surgeries to remove the mesh. *Id.* Her case was part of multi-district litigation involving thousands of plaintiffs. It has been transferred to this court for trial. This memorandum opinion and order deals with a pre-trial motion filed by Robinson to exclude the expert testimony of Pramudji.

Pramudji is a board-certified urologist with a subspecialty board certification in Pelvic Floor Medicine and Reconstructive Surgery. Pramudji filed a Rule 26 expert report on February 26, 2016, and she filed a supplemental report on June 5, 2021. Dkt. 132, Ex. 1, 2. She opines that, relevant to Robinson's motion to exclude, that (1) "TVT-O Type 1 macroporous Prolene

polypropylene mesh is biocompatible, has a minimal inflammatory response, allows for adequate tissue ingrowth and is not associated with a significantly increased risk of infection over that generally associated with SUI and vaginal surgery"; (2) the data does not support that the mesh degrades; and (3) she has not seen evidence of degradation. Dkt. 132, Ex. 1. Additionally, with regard specifically to Robinson, Pramudji opines, after a complete review of Robinson's medical history related to the current issues and a review of deposition testimony, that the "use of TVT-O to treat [Robinson's SUI] was a safe, effective, appropriate and accepted surgical treatment option for her based on the data as discussed in [Pramudji's] general report and this report" and that "recent systematic reviews and metaanalysis involving Ethicon TVT and TVTO continue to support [her] opinion that they are safe, effective, and desirable." Dkt. 132, Ex. 2. Pramudji notes that Robinson reports pain and dyspareunia, but these types of reports "are very common in women" and Robinson's "pain is due to unnecessary revision surgeries with exploration and aggressive removal to appease her desire to have surgery." *Id.* Pramudji notes that Robinson continued to report pain after her revision surgeries, and Robinson claimed to have pudendal neuralgia, "but this has not been demonstrated and it has been ruled out based on her reported pain and the evaluations" in her recent medical records. *Id.* Pramudji believes the cramping Robinson recently complained about "was inconsistent with involvement of the pudendal nerve." *Id.* Pramudji opines that "the TVT-O is not a source of [Robinson's] pain and instead it is more likely from lumbar entrapment and radiculopathy." *Id.* Pramudji concludes that there "is no evidence of mesh defect, degradation, cytotoxicity or adverse effect of the TVTO sling." *Id.*

Robinson argues that Pramudji's opinions exceed the bounds of her qualifications and are founded on insufficient facts and unreliable methodology. Dkt. 132. She asks the court to exclude (1) opinions related to polypropylene, its use in the body, and whether it is subject to degradation,

which Robinson claims are not supported by medical literature in Pramudji's report; (2) opinions related to tissue integration and pore size, which Robinson says are not supported by citations; (3) opinions regarding the TVT-O Instructions for Use ("IFU"), which Robinson asserts are contained in the supplemental report even though the MDL court already ruled Pramudji could not testify about the IFU or product warnings; (4) discussion of Robinson's treating physician's testimony, which Robinson asserts Pramudji mischaracterizes; and (5) testimony about whether the TVT-O caused vulvar pain and pudendal neuralgia because Pramudji allegedly did not consider all relevant material. Dkt. 132.

Ethicon argues that (1) the MDL court already ruled that Pramudji is qualified to offer opinions about degradation; (2) Pramudji did cite a number of peer-reviewed articles to support her opinions on degradation; (3) Pramudji's opinions about pore size and biocompatibility of TVT-O mesh have ample support outlined in her report; (4) Pramudji will not testify about the adequacy of the IFU; (5) Pramudji accurately characterizes Robinson's treating physician's testimony and to the extent Robinson wishes to further explore she can do so on cross examination; and (6) with regard to pudendal neuralgia, the MDL court already ruled that the defense experts do not have to conduct a differential diagnosis because the defense does not bear the burden. Dkt. 138.

The court will first discuss the standard for excluding expert testimony and then address each of Robinson's arguments for exclusion *in seriatim*.

II. LEGAL STANDARD

The U.S. Supreme Court acknowledged in *Daubert v. Merrell Dow Pharmaceuticals* that Federal Rule of Evidence 702 serves as the proper standard for determining the admissibility of expert testimony. 509 U.S. 579, 597-98, 113 S. Ct. 2786 (1993). The party offering expert testimony has the burden to prove by a preponderance of the evidence that the proffered testimony

satisfies the admissibility requirements of Federal Rule of Evidence 702. *Mathis v. Exxon Corp.*, 302 F.3d 448, 460 (5th Cir. 2002). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under *Daubert*, a trial court acts as a "gatekeeper," making a "preliminary assessment of whether the reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93; *see also Kumho Tire v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243-44 (5th Cir. 2002). *Daubert* and its principles apply to both scientific and non-scientific expert testimony. *Kumho Tire*, 526 U.S. at 147. Experts need not be highly qualified to testify, and differences in expertise go to the weight of the testimony, rather than admissibility. *Huss v. Gayden*, 571 F.3d 442, 452 (5th Cir. 2009). Nonetheless, courts need not admit testimony that is based purely on the *ipse dixit* of the expert. *GE v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512 (1997); *Moore v. Ashland Chem. Inc.,* 151 F.3d 269, 276 (5th Cir. 1998).

In addition to being qualified, an expert's methodology for developing the basis of his or her opinion must be reliable. *Daubert*, 509 U.S. at 592-93; *Moore*, 151 F.3d at 276. "The expert's assurances that he [or she] has utilized generally accepted scientific methodology is insufficient." *Moore*, 151 F.3d at 276. Even if the expert is qualified and the basis of her opinion is reliable, the underlying methodology must have also been correctly applied to the case's particular facts for her testimony to be relevant. *Daubert*, 509 U.S. at 593; *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). The party proffering expert testimony has the burden of establishing by

a preponderance of the evidence that the challenged expert testimony is admissible. See Fed. R. Evid. 104(a); *Moore*, 151 F.3d at 276. The proponent does not have to demonstrate that the testimony is correct, only that the expert is qualified, and that the testimony is relevant and reliable. *Moore*, 151 F.3d at 276.

III. ANALYSIS

A. Opinions Related to Polypropylene Degradation and Surface Cracking

Pramudji asserts in her original report that data does not support that TVT-O degrades, and a report about surface cracking used flawed methodology. Dkt. 132, Ex. 1. Robinson argues that these contentions are not supported by medical literature in Pramudji's report and should therefore be excluded. Dkt. 132. She points out that a federal district court in the Middle District of Florida recently agreed that Pramudji did not provide a reliable basis for opining about mesh degradation in the larger population, and the court limited her testimony to discussing only her own clinical experience. *Id.* (citing and quoting *Geery v. Ethicon, Inc.*, No. 6:20-cv-1975-RBD-LRH, 2021 WL 2580144 (M.D. Fla. Apr. 9, 2021)). Robinson additionally asserts that Pramudji is not a pathologist or biomaterials expert and thus has no knowledge, skill, experience, training, or education related to the chemical and physical properties of polypropylene. *Id.*

Ethicon points out that the MDL court already ruled that Pramudji is qualified to opine about mesh's reaction and effect on the human body due to her extensive clinical experience. Dkt. 138. With regard to the contention that Pramudji did not provide medical citations, Ethicon asserts that Robinson "appears to have misread Dr. Pramudji's report," as the quotes Robinson provides are from the beginning of the general report, but Pramudji goes into greater detail later in the report and cites several peer-reviewed articles to support her opinions. *Id.* (citing Dkt. 132, Ex. 1 at 1–5, 62–65). With regard to surface cracking, Ethicon notes that the report on the study

about surface cracking that Pramudji contends is flawed acknowledged that "none of the study's hypotheses regarding degradation could be confirmed in the study." *Id.* (citing Dkt. 138, Ex. A at 264–66). Finally, Ethicon urges the court not to follow the Florida court that partially excluded Pramudji's degradation opinions, arguing that Pramudji's opinions are based on her experience and a review of relevant medical literature, should not have been excluded in that case, and should not be excluded in this one. *Id.*

The court starts first with *Geery*. The *Geery* court determined that Pramudji did 'not cite the relevant 'data' and concede[d] unfamiliarity with polypropylene's chemical processes." 2021 WL 2580144, at *3. The court determined that Pramudji could testify about her own experience but did not provide "a reliable basis to opine generally on mesh degradation in the larger population." *Id.* Here, however, Pramudji cites to studies to support her opinions. She discusses prospective studies that have followed patients with TVT or TVT-O implants for five to seventeen years and concludes that they "show excellent durability and safety with the use of the microporous Prolene polypropylene sling." Dkt. 132, Ex. 1 at 63. If the *Geery* court reviewed the same report that is before this court, the court respectfully disagrees with its conclusion that Pramudji does not provide a reliable basis to opine about degradation in the larger population. The studies she has cited in the report provided to this court are sufficient.

Robinson also takes issue with Pramudji's contention that the report about surface cracking is flawed, but, as Ethicon points out, the authors of the study admitted that none of the hypotheses "concerning degradation of the [polyprolene]" could be confirmed. Dkt. 138, Ex. A at 266. The authors also noted:

> For obvious ethical reasons, this study did not provide the opportunity to analyze vaginal implants from non-pathological situation. Therefore, prediction of normal in vivo material aging or the range of consequences in the clinical state beyond the observed

> samples is not possible. Due to small effective sample size, it is not possible to categorically conclude on the basis of statistical analysis even if a clear tendency is present.

Id. at 269. It appears that any disagreements regarding the interpretation of this studies' results are the result of regular scientific discourse and provide insufficient reason to disqualify Pramudji's opinions.

Robinson's motion to exclude Pramudji's opinions about polypropylene is DENIED.

B. Opinions Related to Tissue Integration and Pore Size

Like with the testimony about degradation, Robinson contends Pramudji does not provide support for her opinions that the mesh is biocompatible, has a minimal inflammatory response, allows for adequate tissue ingrowth, and is not associated with a significantly increased risk of infection. Dkt. 132 (quoting Pramudji's opinion). Robinson asserts that the only citation Pramudji provides is to the National Institute for Health and Care Excellence's Clinical Guideline for 2013, even though new guidelines were published in 2019, and Pramudji has had no personal training on pore size or biocompatibility. *Id.*

Ethicon points out first that the MDL panel has already ruled that Pramudji is qualified to offer these opinions. Dkt. 138 at 4 & n.1. It points out also that Pramudji's report cites to many peer-reviewed articles that TVT and TVT-O have good outcomes and low complication rates, and she specifically quotes from one such article about biocompatibility and pore size. *Id.* She also provides more resources in the addendum. *See id.*

The court agrees with Ethicon. The MDL court already ruled that Pramudji is qualified and her opinions, which are supported by peer-reviewed articles, are reliable. Any additional issues cited by Robinson relating to tissue integration and pore size go to the weight, not the

admissibility, of Pramudji's testimony. The motion to exclude Pramudji's opinions on tissue integration and pore size is DENIED.

C. Opinions Related to the IFU

Robinson notes, and Ethicon agrees, that the MDL court determined that Pramudji is not qualified to offer opinions on the adequacy of the IFU or product warnings. Dkts. 132, 138 (both citing *In re Ethicon*, *Inc.*, MDL No. 2327, 2015 U.S. Dist. LEXIS 115104, at *27-28 (S.D. W. Va. Aug. 25, 2016). Robinson contends, however, that Pramudji offers opinions about the IFU multiple times in her general and supplemental reports. Dkt. 132.

Ethicon asserts that Robinson's argument is essentially that the court should preclude Pramudji from testifying about anything that relates to the IFU or product warnings in general and that this argument takes the MDL court's ruling too far. Dkt. 138. It points out that the MDL court specifically ruled that while Pramudji was unqualified to testify about the adequacy of the warnings, she could "'testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU.'" *Id.* (quoting *In re* Ethicon, 2016 U.S. Dist. LEXIS 115104, at *27). Additionally, Ethicon argues that Pramudji, who has an extensive clinical history of performing more than 900 sling procedures, including 600 mesh cases, is sufficiently experienced to opine about the risks of TVT-O, and she also cites an abundant number of peer-reviewed studies that address the risks of SUI procedures in her supplemental report. *Id.*

The court agrees with Ethicon that Pramudji is qualified to testify about the risks associated with implanting mesh and whether these risks appeared in the IFU. She cannot opine, as she does in the general report, that certain risks "do not need to be incorporated into the TVT-O IFU" or that the "risks are adequately described in the IFU and professional education materials." *See* Dkt. 132, Ex. 1 at 21, 69. However, she may offer an opinion about what is commonly known to

medical professionals. She may also *refer* to the IFU without opining about whether certain warnings should or should not be included in the IFU, as she does in her supplemental report. *See* Dkt. 132 (motion to exclude) at 10 (citing specific testimony from the supplemental report that either merely refers to the IFU or indicates that physicians were warned of certain side effects from sources that include the IFU). *See id.*

Robinson's motion to exclude Pramudji's opinions related to the IFU is DENIED AS MOOT with regard to Pramudji being unqualified to offer certain opinions about the adequacy of the IFU, and it is DENIED with regard to Robinson's request that the court not allow any IFU-related testimony. The parties are instructed to follow the MDL court's ruling on this issue. However, the court realizes that the line is narrow and understands the parties may need clarification from the bench during trial.

D. Opinions Relating to Robinson's Treating Physicians

Robinson contends that Pramudji's supplemental report mischaracterizes the deposition testimony of Robinson's implanting surgeon, Dr. David Kent. Dkt. 132. Specifically, Pramudji states that Kent testified that the TVT-O was safe and effective, that mesh slings were recognized as the standard of care, and that he would not have changed his recommendation to implant the TVT-O. *Id.* (citing Dkt. 132, Ex. 2 (supplemental report)). Robinson points out that these statements were based on what Kent knew at the time of the implant, and that he also testified that if he had known there was a risk of permanent nerve damage and long-term severe chronic pain, he would have told Robinson. *Id.* Robinson also argues that Pramudji misstates Robinson's medical records relating to pudendal neuralgia, indicating that pudendal neuralgia had been ruled out when Robinson received a prescription for pudendal neuropathy after pelvic floor therapy did

not work. *Id.* Robinson asserts that Pramudji therefore does not reliably represent the opinions of Robinson's physicians and should be precluded from testifying about it. *Id.*

Ethicon argues that Robinson does not mischaracterize the record. Dkt. 138. It notes that Robinson appears to argue that Pramudji should have discussed more of Kent's testimony and that if Robinson wants to bring out more of the testimony, she is free to do so on cross examination. *Id.* As far as the pudendal neuralgia, Ethicon notes that Pramudji summarizes Robinson's more recent medical records in the supplemental report, and that Pramudji noted that the symptoms expressed during the appointments the doctor was discussing were not consistent with pudendal nerve issues. *Id.* Ethicon argues that if Robinson would like to cross examine Pramudji about Robinson's medical records from earlier that demonstrate pudendal nerve issues, she is free to do so, but a discussion about what records from a different appointment demonstrate does not undercut the scientific validity of Pramudji's interpretation of the recent visits. *Id.*

The court agrees with Ethicon that the issues Robinson presents relating to Pramudji's consideration of materials relevant to Robinson's diagnosis and the portions of testimony Pramudji considered are appropriate areas for cross examination and go to the weight rather than the admissibility of the evidence. The motion to exclude the testimony relating to Robinson's treating physicians and medical records is DENIED.

E. Opinions About Injuries Pramudji Does Not Address

Robinson asserts that Pramudji fails to mention the Nantes Criteria and does not consider symptoms described by Robinson in her deposition or Robinson's responses to the vulvar pain function questionnaire that are consistent with Pudendal neuralgia, and thus should be precluded from opining about whether Robinson has pudendal neuralgia. Dkt. 132. Robinson argues

Pramudji's opinions about Robinson's diagnosis are not being grounded in valid scientific methodology and speculative at best. *Id.*

Ethicon takes issue with how Robinson characterizes Pramudji's report, but argues that, regardless, Pramudji was not required to perform a differential diagnosis "'to identify the specific cause of an injury'" because the defense does not bear the burden of proving causation. Dkt. 138 (citing *Springer v. Ethicon*, 2017 U.S. Dist. LEXIS 55329, at *4 (S.D. W. Va. Apr. 10, 2017)).

The court finds that Robinson's arguments go to the weight and not the admissibility of Pramudji's testimony. Robinson is free to cross examine Pramudji to explore the bases of her conclusions and demonstrate any perceived flaws to the jury. The motion to exclude the Pramudji's testimony relating to pudendal neuralgia is DENIED.

IV. CONCLUSION

Robinson's motion to exclude Pramudji's testimony is DENIED.

Signed at Houston, Texas on March 4, 2022.

Gray H. Miller
Senior United States District Judge